IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, Plaintiff, v. THOMAS L. CROFUT and JUDITH H. CROFUT, individuals d/b/a GOOD FLOW HONEY AND JUICE CO., Defendants.	Civil No. 07-CV-00996-SS CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Thomas L. Crofut and Judith H. Crofut, (collectively, "Defendants"), individuals doing business as Good Flow Honey and Juice Co. ("Good Flow"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act").

3. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food within the meaning of

21 U.S.C. § 321(f), namely unpasteurized, fresh-squeezed, juices and juice blends ("juice"), to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), after shipment in interstate commerce, in that the juice has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

4. Defendants and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from receiving, processing, preparing, packing, holding, or distributing juice, at or from Defendants' juice processing plant located at 2601 East Cesar Chavez Street, Austin, Texas ("Defendants' plant"), and at or from any other locations at which Defendants may receive, process, prepare, pack, hold, or distribute juice, unless and until:

A. Defendants retain, at Defendants' expense, an independent person or persons ("expert"), who by reason of background, education, training, and experience, is qualified to develop and implement a Hazard Analysis Critical Control Point ("HACCP") plan for juice. The expert shall be without personal

or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity of the expert as soon as they retain such expert;

B. Defendants have the expert develop and submit to FDA for review written HACCP plans for each type of juice processed by Defendants, consistent with 21 C.F.R. § 120.8(a) - (c).

(1) Pursuant to 21 C.F.R. § 120.24(a), such HACCP plans shall include control measures that will consistently produce, at a minimum, a 5-log reduction in the "pertinent microorganism," as defined in 21 C.F.R. § 120.24(a).

(2) Pursuant to 21 C.F.R. § 120.24(b), the 5-log reduction process identified in Defendants' HACCP plans will be accomplished through treatments that are applied directly to the juice. For citrus juices, however, the 5-log reduction process identified in Defendant's HACCP plans may use treatments applied to the fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning, as defined in 21 C.F.R. §§ 120.3(a) and (f), and will be accomplished within Defendant's production facility.

(3) Pursuant to 21 C.F.R. § 120.25, when Defendants utilize in their production of citrus juice a surface

treatment process to achieve the 5-log reduction, Defendants shall ensure that their unpasteurized, finished juice products containing citrus juice are analyzed for biotype I *Escherichia coli* ("*E. coli*") in accordance with the frequency and methods of analysis proscribed in 21 C.F.R. § 120.25, and when positive samples are identified, Defendants shall comply with the corrective actions specified in 21 C.F.R. § 120.25(c) and (d); and

C. Defendants have the expert certify in writing to FDA that the control measures in Defendants' HACCP plans are adequate to consistently produce, at a minimum, a 5-log reduction in the "pertinent microorganism," as defined in 21 C.F.R. § 120.24(a); and

D. FDA has approved, in writing, the HACCP plans developed by the expert, and notified Defendants, in writing, that the HACCP plans appear to satisfy the requirements of Paragraphs 4(A) - (C) of this Decree, the Act, and 21 C.F.R. § 120. It is expected that FDA's review of the HACCP plans and expert certification submitted pursuant to Paragraphs 4(B) and (C) shall be completed within a reasonable time after such documents are received, or as soon thereafter as is reasonably practicable in the event that FDA representatives are attending to other FDA matters.

5. After Defendants receive written notification from FDA pursuant to Paragraph 4(D) that they appear to be in compliance with Paragraphs 4(A)-(C) of this Decree, the Act, and 21 C.F.R. § 120, Defendants and each and all of their agents, employees, attorneys, successors, assigns and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree, are permanently restrained and enjoined from:

(A) directly or indirectly doing or causing any article of food, within the meaning of 21 U.S.C. § 321(f), to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce; and

(B) failing to implement and continuously maintain the requirements of this Decree.

6. No later than 120 days after Defendants receive written notification from FDA pursuant to Paragraph 4(D) that they appear to be in compliance with Paragraphs 4(A)-(C) of this Decree, the Act, and 21 C.F.R. § 120:

A. Defendants must fully implement to FDA's satisfaction the written HACCP plans developed by the expert and approved in writing by FDA; and

B. Defendants must have the expert validate and

certify in writing to FDA that the HACCP plans have been fully implemented, and the control measures in Defendants' HACCP plans have consistently produced, at a minimum, a 5-log reduction in the "pertinent microorganism," as defined in 21 C.F.R. § 120.24(a). Upon receiving the expert's certification, FDA will inspect, at Defendants' expense, the Defendants' plant, including all records relating to the receipt, processing, preparation, packing, holding, and distribution of juice, to confirm that the processes and controls used for the receipt, processing, preparation, packing, holding, and distribution of juice appear to be in compliance with this Decree, the Act, and 21 C.F.R. Part 120. If FDA determines that the firm is not in compliance with any of these requirements, it may, in its discretion, order Defendants to cease operations pursuant to Paragraph 11 of this Decree.

7. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' plant at its current location or at any new locations, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include, but are not limited to, taking photographs and samples and examining and copying all records that relate to the receipt, processing, preparation, packing, holding, and distribution of

juice. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

8. Defendants shall immediately provide any information or records to FDA, upon request, regarding the receipt, processing, preparation, packing, holding, or distribution of juice. Defendants shall maintain a copy of their HACCP plan and all records required by their HACCP plan and 21 C.F.R. Part 120 at the plant in a location where they are readily available for reference and inspection by FDA representatives. All records required to be kept by the HACCP plan and by regulation shall be retained for at least three (3) years after the date they are prepared and shall be presented immediately to FDA investigators upon request.

9. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $81.61 per hour and fraction thereof per representative for inspection work; $97.81

per hour or fraction thereof per representative for analytical or review work; $0.505 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

10. If any Defendant violates this Decree and is found in civil or criminal contempt, that Defendant shall, in addition to other remedies, reimburse Plaintiff for its attorney fees (including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings.

11. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, the analyses of samples, a report or data submitted by Defendants or the expert, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to

immediately cease receiving, processing, preparing, packing, holding, and distributing juice, and Defendants shall immediately comply with any such written orders. In addition, Defendants shall, as and when FDA deems necessary, recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers. All costs of such recall(s) and corrective actions shall be borne by Defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in Paragraph 9.

12. Any cessation of operations as described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree.

13. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of Defendants' agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance stating the fact and manner of compliance with the

provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Decree.

14. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including: a reorganization, relocation, dissolution, assignment, sale, or gift resulting in the emergence of a successor entity or corporation; any other change in the structure, ownership interests, or identity of Good Flow Honey and Juice Co., or any other current or future juice processing business of Defendants; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such sale or change of business.

15. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the Director, FDA Dallas District Office, 4040 North Central Expressway, Dallas, Texas 75204-3145.

16. Defendants shall abide by the decisions of FDA, which decisions shall be final. When contested by Defendants, FDA decisions under this Decree shall be reviewed by the Court under

the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record that was before FDA at the time the decision was made. No discovery shall be taken by either party.

17. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

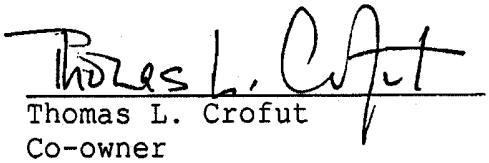
SO ORDERED:

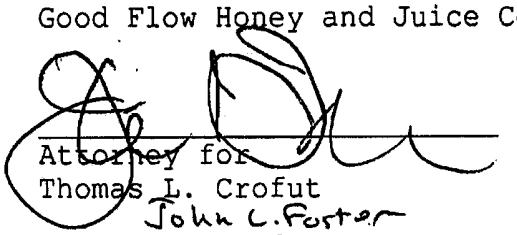
Dated this 6th day of May, 2008.

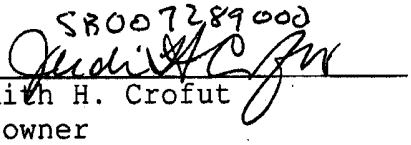
Sam Sparks
United States District Judge

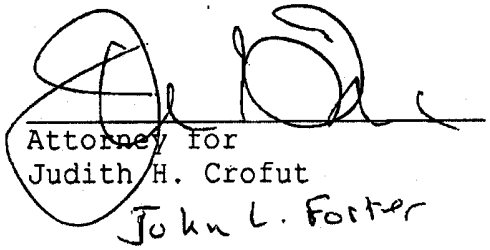
We hereby consent to the entry of the foregoing Decree.

For Defendants:

X 
Thomas L. Crofut
Co-owner
Good Flow Honey and Juice Co.


Attorney for
Thomas L. Crofut
John C. Foster
SB007289000

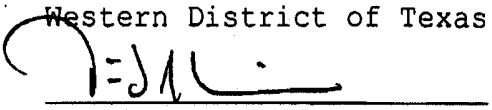
X 
Judith H. Crofut
Co-owner
Good Flow Honey and Juice Co.


Attorney for
Judith H. Crofut
John L. Foster
SB # 007289000

For Plaintiff:

JEFFREY S. BUCHOLTZ
Acting Assistant
Attorney General

JOHNNY SUTTON
United States Attorney
Western District of Texas


DAVID SULLIVAN
Trial Attorney
Office of Consumer Litigation
Department of Justice
P.O. Box 386
1331 Pennsylvania Ave., N.W.
Room 950 North
Washington, D.C. 20004

OF COUNSEL:

JAMES C. STANSEL
Acting General Counsel

GERALD F. MASOUDI
Associate General
Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel for
Litigation

MICHAEL SHANE
Associate Chief Counsel for
Enforcement

United States Department of
Health and Human Services
Office of the General Counsel
5600 Fishers Lane, GCF-1
Rockville, MD 20857
(301) 827-2802